

REMARKS

Claims 5 and 6 are pending. Claim 5 has been amended. No new matter has been introduced thereby. A period has been introduced at the end of claim 5, rendering the objection to this claim moot.

Rejection Under 35 U.S.C. §112, Second Paragraph

Claims 5 and 6 have been rejected as indefinite for reciting “a suitable isocyanate and in a suitable solvent,” and “low temperature,” in the absence of a standard to ascertain the requisite degrees of suitability of the reagents, solvents, and low temperature. Applicants submit that the rejection is moot, upon the amendment presented herein.

Rejection Under 35 U.S.C. §103(a) Over Arora et al. (United States Patent No. 5,637,570) in view of Bouveng (Acta. Chem. Scand., 1961, 15, pp 96-100)

The Examiner's position is that processes disclosed in Arora et al. in combination with the disclosure of Bouveng, makes applicants' instant claims obvious. As an initial matter, it is clear that Arora et al. differs from the instant claims, in that the disclosure of Arora et al. is directed to compounds wherein the sugar is not substituted with a carbamate moiety.

Further, there is no teaching or suggestion in Arora et al. to employ processes to create a carbamate group at the 4-position of the compound of Formula I. The disclosure of Arora et al. shows that R₂ in the -OR₂ group can take the values of hydrogen, C₁₀-C₁₅ alkyl, -(CH₂)_{n3}-N-[cyclic alkyl group optionally containing an oxygen atom] or -(CH₂)_{n5}-N(CH₃)₂, wherein n₃ and n₅ can be 2-6 and 2-4 respectively.

The disclosure of Arora et al. does not appear to disclose, suggest or provide motivation for modification of the molecule of Formula I at any position in the structure, beyond what is mentioned as possible for R, R₁ or R₂. Certainly it does not, at any point, disclose, suggest, or

provide any motivation whatsoever for any further modification of the molecule at the 4-position of the structure of Formula I. Indeed, the Examiner has not provided any evidence of motivation for such modification of the compounds or methods of Arora et al.

Absent any statement in Arora et al. to modify the disclosed compounds in any way at the 4-position, the Examiner's assertion that applicants' claimed methods directed to the production of compounds including carbamate at this position are obvious would appear to be no more than impermissible hindsight. No *prima facie* case of obviousness has been made out. Applicants respectfully request reconsideration and withdrawal of the rejection.

The Examiner asserts that "[i]t would have been obvious to person having ordinary skill in the art at the time the invention was made, to modify the process for conversion of the 4-hydroxy group to its corresponding nitrogen containing heterocyclic moiety of Arora in view of the teachings of Bouveng to a process of conversion of a free hydroxyl group to its corresponding carbamate by treating with an isocyanate reagent because Arora discloses that the said compounds exhibit greater potency for cancer treatment and provides ease of oral administration when the 4-OH is substituted with a nitrogen containing heterocyclic moiety." (Office Action, page 4; emphasis added).

Applicants strongly and respectfully disagree with the quoted statement to the extent that the Examiner is suggesting that Arora et al. discloses applicants' compounds, suggests applicants' compounds, or contains any disclosure or suggestion of the usefulness of applicant's compounds or any claimed method to make applicants' compounds. As discussed above, Arora et al. contains no suggestion or motivation for modification of the compounds of Formula I, and certainly no such suggestion for modification at the 4-position of the structure. Thus, methods of making applicants' compounds are also not suggested thereby.

Regarding Bouveng, the publication appears to disclose the investigation of the distribution of O-acetyl groups in glucuronoxylan from birch wood using phenylcarbamoyl groups as protective substituents (see Abstract). According to the Dictionary of Cell and Molecular Biology – Online! (Internet address: <http://www.mblab.gla.ac.uk/~julian/dict2.cgi?2691>), glucuronoxylan is a

“hemicellulosic plant cell-wall polysaccharide containing glucuronic acid and xylose as its main constituents. Glucuronoxylan has a β -(1-4)-xylan backbone, with 4-O-methylglucuronic acid side-chains. Arabinose and acetyl side-chains may also be present. Major polysaccharide of angiosperm wood (hardwood).”

Further information on the structure of glucuronoxylan may be derived from an article located online (Internet address: <http://bab.portlandpress.com/bab/031/0061/bab0310061.htm>) at Biotechnology and Applied Biochemistry (vol. 31, pp 61-68, (2000)), which states that

“[x]ylan is the main hemicellulose in plant cell walls. It is a linear polysaccharide consisting of D-xylose residues linked by β -1,4 bonds with a variety of substituents in carbons 2 and 3 of the main xylose units. The side groups are linked to the main chain by either glycosidic (L-arabinofuranose, 4-O-methyl-D-glucuronic acid) or ester (acetic acid) bonds. The actual structure of xylan depends on its origin.” (Introduction)

It does not appear that the cited reference is at all relevant to the obviousness (*vel non*) of the claimed processes. There does not appear to be any disclosure or suggestion of the methods of making 2,3-O-isopropylidene- α -L-xylo-2-hexulofuranose compounds of the present invention. The teaching of the reference, namely that a 4-hydroxyl group can be transformed to a phenylcarbamoyl group in a compound of no clear relevance to applicants’ claimed methods, cannot be seen to constitute a *prima facie* case of obviousness in the present case.

There is no suggestion or motivation contained in the Bouveng reference to use the claimed methods to produce applicants’ compounds. Again, absent such suggestion or

motivation, the Examiner's position that it would have been obvious to combine Arora et al. with Bouveng would appear to be nothing more than impermissible hindsight. Applicants respectfully request that the rejection be reconsidered and withdrawn.

CONCLUSION

Applicants submit that the claims are allowable as written, and respectfully request a Notice of Allowance as the next mailing from the Office.

Respectfully submitted,
ARORA *et al.*

By: 
George E. Heibel, Reg. No. 42,648

Date: June 7, 2004

Ranbaxy Inc.
600 College Road East, Suite 2100
Princeton, New Jersey 08540
Tel: (609) 720-5334
Fax: (609) 514-9779